

REMARKS

This is in full and timely response to the above-identified Office Action. The above listing of the claims supersedes any previous listing. Favorable reexamination and reconsideration are respectfully requested in view of the preceding amendments and the following remarks.

Claim Status

Claims 9-13 stand un-amended and as they were finally rejected

Claim Rejections Under 35 U.S.C. § 102/103

1) The rejection of claims 9-13 under 35 USC § 103(a) as being unpatentable over Meade in view of Sorge or Ullman et al., is respectfully traversed.

In this rejection it is acknowledged that Meade does not specifically teach forming a double strand hybrid by applying heat to facilitate the dissociation of the binding partner and binding ligand followed by subsequent cooling. To overcome this admitted shortcoming, Sorge and Ullman et al. are cited.

In traverse, it is pointed out that Meade relates to a method of detecting target matter to be analyzed through the combination of the target matter to be analyzed with an oxidation-reduction active complex. However, the claimed subject matter differs in that it detects target DNA, through a complementary difference among signaling DNA, target DNA and probe DNA. Nowhere does Meade specifically disclose that target DNA can be detected via the complementary difference of signally DNA, target DNA and probe DNA. Notably, Meade neither discloses nor suggests the subject matter of claim 9 wherein the complementarity of signal DNA and target DNA is made higher than the complementarity of probe DNA and signaling DNA.

Thus, aside from the adding the steps of heating and cooling in order to promote hybridization, there is a clear and definite difference between what is claimed and the disclosure of Meade.

Although Meade is the only reference specifically discussed, it is deemed sufficient to show the shortcoming of the rejection which the secondary references are unable to rectify. The Examiner is therefore requested to avoid an improper reliance on the frequently cited case of *In re Keller* (642 F.2d 413, 208 USPQ 871 (CCPA 1981)) and the position that attacking the references individually fails to establish a proper traverse. Indeed, the main thrust of *In re Keller* is that “the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference, nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.” (Emphasis added)

Indeed, the “attacking references individually” is mentioned in connection with *In re Young* 56 CCPA 757, 403 F.2d 754, 159 USPQ 725 (see paragraph [6] on page 882 of USPQ 208) and is definitely not the main basis of the *In re Keller* decision. *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) merely cites the *In re Keller* decision, which as noted above, imports this relatively trivial issue from *In re Young*.

2) The rejection of claims 9-13 under 35 USC § 103(a) as being unpatentable over Wohlsadter et al. in view of Hill et al. and/or Ullman et al., is respectfully traversed.

The key issue with respect to the disclosure of Wohlsadter et al. centers around whether direct labeling of the DNA is carried out or not. More specifically the Wohlsadter et al. reference is such that in order for the electrode to sense the specific reaction to the enzyme etc., which is attached to the DNA, an electrochemically active material is used as a medium between the enzyme and the electrode. However, in direct contrast, with the claimed invention, a direct reaction between the material and the electrode can be observed by attaching the electrochemically active material direction to the DNA.

Therefore, in Wohlsadter et al. if the electrochemically active material is dissolved in the solution, the electrochemically active material would become attached to the DNA. That is to say, in Wohlsadter et al. separate steps of making an electrochemically active material solution and subsequent immersion are required. With the claimed invention such separate steps are not required.

In this rejection Hill is cited to show that measuring currents were well known at the time of invention. This of course raises the question as to why this was not disclosed in Wohlsadter et al. if in fact the comparative complementation were to be inherent, as purported in this office action.

Indeed Wohlsadter et al. discloses an electroluminescent technique. Even the use of porous electrodes (see column 58 lines 22-37) are such as produce electroluminescent response upon a voltage being applied to the electrodes. Viz.:

5.14. ECL Assays Employing The Capture Of Particles On Porous Electrodes

The invention includes a method for performing an **electrochemiluminescence** binding assay in which a complex is formed. The complex includes, at least, a particle and a label compound capable of electrochemiluminescence. The complex may also include ligands used in electrochemiluminescence assays as disclosed for example in Yang H. J. et al., BioTechnology, 12, (1994), 193-194. The method includes the steps of (a) forming the complex; (b) collecting the complex by filtration on a porous, conductive electrode; (c) **inducing the label compound in the collected complex to luminesce by imposing a voltage on the electrode**; and (d) **detecting the emitted luminescence** from the electrode.

In another method for performing an electrochemiluminescence binding assay, the particle capable of complexing with a component of an electrochemiluminescence assay is first collected on a porous conductive electrode. Then the sample containing the analyte of interest is passed through the porous, conductive electrode and forms complex on the particle theretofore collected on the electrode. Then the label compound is induced to luminesce by imposing a voltage on the electrode and the emitted luminescence is detected to measure the presence of the analyte of interest. In a preferred embodiment the porous, conductive electrode will be pre-prepared with particles incorporated therein and upon use the sample containing analyte of interest will be passed through the electrode to form the complex.

Why, in light of this disclosure would the hypothetical person of ordinary skill be motivated to consider measuring voltage as compared to light emission?

As to the Sorge reference, it seems that if the heating/cooling were to be inherent, then there would be some disclosure/hint in the Wohlsadter et al. reference to this effect. On the other hand, it is inherent and is not disclosed *per se*, it may be well concluded that the Wohlsadter et al. is not enabling at least for this aspect of the process which is disclosed in this reference.

For at least these reasons, the claimed subject matter is deemed patentable over the above-discussed combinations of art.

Conclusion

Therefore, all objections and rejections having been addressed, it is respectfully submitted that the present application is in condition for allowance and a Notice to that effect is earnestly solicited.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 07-1337 and please credit any excess fees to such deposit account.

Respectfully submitted,

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